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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Improved Live-Attenuated Vaccine for Respiratory Syncytial Virus

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Commercialization Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Summary Information section of this notice to Codagenix, Inc. (Codagenix), having a place of business in Farmingdale, New York, U.S.A.

DATES: Only written comments and/or applications for a license which are received by the National Institute of Allergy and Infectious Diseases' Technology Transfer and Intellectual Property Office on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Commercialization Patent License should be directed to: Peter Soukas, Technology Transfer and Patent Specialist, Technology

Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, National Institutes of Health; Email: ps193c@nih.gov; Telephone: (301) 496-2644; Facsimile: (240) 627-3117.

SUPPLEMENTARY INFORMATION:

Intellectual Property

U.S. Provisional Patent Application Number 63/023,949, filed May 13, 2020 and PCT Patent Application Number PCT/US2021/32305, filed May 13, 2021, entitled "Improved Live-Attenuated Vaccine for Respiratory Syncytial Virus (RSV) Bearing Codon-Pair Deoptimized NS1, NS2, N, P, M and SH Genes and Additional Point Mutations in the P Gene," [HHS Reference No. E-104-2020-0]; and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive licensed territory may be worldwide, and the field of use may be limited to: "Live-attenuated codon-deoptimized human respiratory syncytial virus vaccine."

RSV is the most important viral agent of severe respiratory disease in infants and young children worldwide and also causes substantial morbidity and mortality in older adults. RSV is estimated to cause more than 33 million lower respiratory tract illnesses, three million hospitalizations, and nearly 200,000 childhood deaths worldwide annually, with many deaths occurring in developing countries. However, despite the prevalence of RSV and the dangers associated with infection, no RSV vaccine has been successfully developed to date. Accordingly, there is a public health need for RSV vaccines.
This vaccine candidate comprises live RSV that was attenuated by subjecting the protein-coding sequences of the viral NS1, NS2, N, P, M, and SH genes to codon-pair

deoptimization, which resulted in many nucleotide substitutions that were silent at the amino acid level but conferred attenuation. In addition, specific amino acid substitutions were identified and introduced into the P protein that improved attenuation and genetic stability. Genetic stability was confirmed in vitro, and attenuation was confirmed in experimental animals.

This live-attenuated RSV vaccine is designed to be administered intranasally by drops or spray to infants and young children. Based on experience with other live-attenuated RSV vaccine candidates, the present candidates are anticipated to be well tolerated in humans and are available for clinical evaluation. The National Institute of Allergy and Infectious Diseases has extensive experience and capability in evaluating live-attenuated RSV vaccine candidates in pediatric clinical studies.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License applications submitted in response to this Notice will be presumed to contain business confidential information, and any release of information in these license applications will be made only as required and upon a request under the *Freedom of Information Act*, 5 U.S.C. 552.

Surekha Vathyam,
Deputy Director,
Technology Transfer and Intellectual Property Office,
National Institute of Allergy and Infectious Diseases.
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